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Director Approval _____Date_____

UCSF Medical Center Clinical Laboratories	Point of Care Testing Manual

CHOLESTECH LDX SYSTEM

I. PURPOSE

For the quantitative determination of total cholesterol, HDL cholesterol, triglycerides, and glucose may be performed on adult and pediatric patient samples.

II. PRINCIPLE

The Cholestech LDX System combines enzymatic methodology and solid-phase technology to measure total cholesterol, HDL cholesterol, triglycerides, glucose, ALT and AST. Samples used for testing can be whole blood from venipuncture or fingerstick (collected in a lithium heparin coated tube/ capillary tube). The sample is applied to a Cholestech LDX cassette. The cassette is then placed into the Cholestech LDX Analyzer. A unique system on the cassette separates the plasma from the blood cells. A portion of the plasma flows to the right and left sides of the cassette where it is transferred to reaction pads. The Cholestech LDX Analyzer measures the resultant color in all the reactions by reflectance photometry (the amount of light reflected from a solid surface.
A brown magnetic stripe on each cassette contains the test names, instructions to the Analyzer for running the tests on the cassette, and calibration information for converting the colour reading to analyte concentration in mg/dL for lipid profile and glucose.

III. REAGENTS AND EQUIPMENT

A. Cholestech LDX Analyzer and power supply.
B. Cholestech LDX test cassettes.
   1. Lipid Profile
   2. Lipid Profile plus Glucose
   a. Cassettes must be stored in the sealed foil pouches.
   b. Cassettes may be used until the date printed on the pouch when stored in a refrigerator 2°C to 8°C (36°F to 46°F), or the cassettes may be stored up to 30 days at room temperature (9 – 30°C / 48 – 86°F).

c. Once cassettes have been stored at room temperature they should not be returned to the refrigerator. Write the new expiration day on the cassette box. The new expiration date is the date the cassettes are placed at room temperature plus 30 days.
d. Do not use cassettes beyond the printed expiration date, or cassettes that had been stored at room temperature for more than 30 days.
e. Do not reuse cassettes.

C. Cholestech LDX Mini-Pet Pipette or similar pipette with disposable tips – to place blood and quality control material into the cassette. A drop of 35 μl (micro liters) is required.
D. Optics Check Cassette – used to check the optical system of the Analyzer daily. Store at room temperature in the case provided.
E. Quality control materials
   a. Lipid/Glucose Level 1 and Level 2 Controls for Lipid Profile▪Glucose

Note: Controls are stored upright and refrigerated (2° - 8^oC or 36° - 46^oF). Unopened vials are expected to give stable results through the expiration date printed on the box. Opened vials are stable for 30 days refrigerated at 2° - 8^oC or 36° - 46^oF. Do not freeze. Minimize exposure to strong light.

F. Ambient Room Temperature Thermometer- Temperature range: 20 ^oC to 31 ^oC (68^oF to 88^oF)
G. Reagent Refrigerator- Temperature range: 2^oC to 8^oC (36^oF to 46^oF).
H. Gloves
I. Lancet for finger stick
J. Cholestech LDX Capillary Tubes (with lithium heparin anticoagulant)
K. Cholestech LDX Capillary Plungers
L. Biohazard Waste Container
M. Kimwipes
N. Alcohol swabs and gauze for clean puncture site

IV. SPECIMEN

A. Sample volume: 35 uL whole blood from Lithium Heparin vacutainers or capillary tubes
B. Whole blood collected in a Lithium Heparin vacutainers should be used within thirty minutes of draw
C. Capillary tube (with lithium heparin anticoagulant) for the Cholestech LDX test should be used within 5 minutes of collection.
D. Fluoride, oxalate, citrate and EDTA anticoagulants will interfere with the total cholesterol, HDL cholesterol, and triglyceride test and should not be used.
E. Blood collection tubes whose stoppers are lubricated with glycerol should not be used for collection of specimens for the lipid profile plus glucose panels.
F. Whole blood samples should be at room temperature for testing. Mix all samples by inverting gently 7-8 times before testing.

G. **Patients should fast for 9 – 12 hours before the sample is collected.**

V. QUALITY CONTROL

A. Optic Check Cassette

1. Cholestech LDX Optics Check Cassette with known reflectance value is used to check the optical system of the Analyzer. The cassette should be stored at room temperature in its case and cannot be allowed to become wet, dirty, or scratched.
2. Optics check must be run each day of use.
3. Optics check must be run after the Analyzer is serviced or moved.

B. Temperature

1. Refrigerator temperature must be monitored and recorded on the temperature log daily.
2. Room temperature where the Cholestech is stored or used must be monitored and recorded on the temperature log daily.

C. Liquid QC Controls

1. Run two levels of controls on each day of patient testing.
2. Run two levels of controls on each new shipment of cassettes.
3. Run two levels of control on each new lot of cassettes.
4. Run two levels of control on each new box.
5. Run controls if you think cassettes may not have been stored properly.

Follow the instructions that come with the controls. Check the expiration date before use. Opened vials are stable for 30 days refrigerated.

Verify that QC control results are in range before testing patients.

1. If controls are out of range for one or more analytes, then repeat the controls.
2. If repeat controls are still out of range, take primary instrument out of service and use back-up instrument.
3. Run liquid controls on the back-up instrument; if controls out of range, repeat. If controls fail again (possible cartridge problem), the out of control analyte(s) cannot be reported for that day.
4. Next day of use, open and run a new set of liquid controls. If controls are still out after two trials on both instruments, the cartridge is the suspected problem. The out of control analyte(s) should not be reported until a new lot of cartridges is obtained and shown to pass liquid quality control.

Note: All opened reagent boxes and control vials must be dated and initialed upon opening.

VI. PROCEDURE

Note: Prior to patient testing, use two patient identifiers to verify patient identification and explain procedure to patient and/or family.

A. Perform an Optics Check before running patient samples each day. The optics cassette is placed in the Analyzer and run as a specimen. The data printed for each of the 4 channels is then checked against the acceptable ranges printed on the cassette. Maintain a log sheet for the Optics Check cassette data.

B. Perform two levels of liquid controls each day of patient testing. Record results on the QC log sheet.

C. Let test cassette sit at room temperature for ten minutes.

D. Remove the cassette from its pouch. Do not touch the black bar or the brown stripe. Hold the cassette by the short side only. Put the cassette on a flat surface.

E. Press **RUN.** In a few seconds the screen will read:

Selftest running

Selftest OK

F. The cassette drawer will open. The screen will read:

Load cassette and press RUN

G. Place the sample into the cassette well using a Cholestech LDX Capillary tube for fingerstick samples or the Cholestech Mini-Pet Pipette for controls or venous blood samples.

Note: Fingerstick samples must be applied within 5 minutes after collection or the blood will clot.

H. Keep the cassette flat after the sample has been applied.

I. Place the cassette into the drawer of the Analyzer immediately. The black bar must face the Analyzer. The brown stripe must be on the right.

J. Press **RUN**. The drawer will close. During the test the screen will read:

[Test Name(s)]
Test Running***

K. Put everything that touched the blood sample or control in a biohazard waste container.

L. When the test is complete, the Analyzer will beep. The screen will read:

[Test Name(s)]=###
warnings

M. When the results are outside the measuring range, the screen will read:

[Test Name] >### or [Test Name] <###

N. If there is a problem with the test, a message will appear on the screen. See the troubleshooting section of the Cholestech LDX User Manual if this happens.

O. When the drawer opens, remove the cassette. Dispose of it in a biohazard waste container. Leave the analyzer drawer empty when not in use.

P. Verifying patient identification, using two patient identifiers, attach patient preprinted "IDX" label to the printer data. Record the results in the patient's medical record chart and give printed results to the Physician.

Q. To run another cassette, press **RUN**. The screen will read:

Load cassette and press RUN

R. Repeat the test procedure.

S. Otherwise, after 4 minutes a beep will sound and the screen will read:

System Timeout RUN to continue

T. If the **RUN** button is not pushed within 15 seconds the drawer will close and the screen will go blank.

VII. REPORTING OF RESULTS

Results from the printer are given to the Physician as he/she sees the patient at the time of their appointment. The Cholestech LDX is programmed to report in mg/dl for lipid profile and glucose. Test results will show on the screen when the test is complete. Calculated results are shown after the **DATA** button is pressed.

Results for out of control analytes are not reported.

<u>Expected Values</u>

Total Cholesterol Guidelines:

Children and Adolescents (<20y/o):

Acceptable <170 mg/dL
Borderline 170-199 mg/dL
High >199 mg/dL

Adults (>19y/o):

Desirable <200 mg/dL
Borderline 200-239 mg/dL
High >239 mg/dL

HDL Cholesterol Guidelines:

Acceptable >39 mg/dL
Higher risk <40 mg/dL
Lower risk >59 mg/dL

Estimating the risk of atherosclerotic heart disease from the ratio of *total/HDL Cholesterol* is no longer recommended by many experts, who believe that HDL cholesterol is most useful when employed as part of the assay for LDL Cholesterol rather than by itself. Others believe that the ratio of total/HDL cholesterol may better predict coronary risk (high risk males:>6.0-7.0; high risk females: >5.6-6.0).

Triglyceride Guidelines:

The ATP 11 of the NHLBI has recommended these guidelines for fasting triglyceride levels:

Desirable: <150 mg/dL
Borderline high: 150-199 mg/dL
High: 200-499 mg/dL
Very high: >=500 mg/dL

LDL Cholesterol Guidelines:

Method: Calculated (Friedewald formula)
Children and Adolescents (<20 y/o):

Acceptable <110 mg/dL
Borderline high 110-129 mg/dL
High >129 mg/dL

Adults (>19 y/o): Optimal for patients with CHD or CHD risk equivalent <100 mg/dL

Desirable <130 mg/dL
Borderline high-risk 130-159 mg/dL
High-risk 160-189 mg/dL
Very high-risk >=190 mg/dL

NOTE: **This estimate of LDL is not reliable if the triglycerides are > 400**

Glucose Guidelines:

The American Diabetes Association has modified the criteria for fasting plasma glucose (FPG) and the diagnosis of diabetes mellitus.

FPG 70 – 99 mg/dL	normal fasting glucose
FPG 100 – 125 mg/dL	impaired fasting glucose
FPG >125 mg/dL	provisional diagnosis of diabetes Confirmed by one of the three methods below.

The revised criteria for diagnosis of diabetes.

- Symptoms of diabetes plus casual plasma glucose concentration ≥200 mg/dL (11.1 mM/L). Casual is defined as any time of day without regard to time since last meal. (The classic symptoms of diabetes include polyuria, polydipsia, and unexplained weight loss).
- FPG >125 mg/dL (7.0 mM/L). Fasting is defined as no caloric intake for at least 8 hours.
- 2 hr post glucose load ≥200 mg/dL during an oral glucose tolerance test. The test should be performed as described by WHO (World Health Organization) using a glucose load containing the equivalent of 75g anhydrous glucose dissolved in water.

Any of the above abnormal glucose levels must be confirmed, on a subsequent day, by any one of the three methods listed above. When screening for diabetes, any abnormal glucose results should be referred to a physician for further follow-up.

Glucose Panic Value Reporting

Panic Value ranges:
Critical Adult/Pediatric <60 or >400 mg/dL

Notify physician and if this is a new finding, send sample to Clinical Lab for confirmatory testing. Document actions taken.

VIII. MAINTENANCE

A. Clean the outside of analyzer with a clean damp cloth. If necessary, a mild detergent or disinfectant (such as a 5% bleach solution) may be used. ***Do not*** immerse the Analyzer in water or other cleaning fluid. ***Do not*** use any abrasive cleanser.
B. When necessary, clean inside the cassette drawer with a cotton swab moistened with water, a 70% isopropyl alcohol solution, a 5% bleach solution or disinfectant. Dry with a second (unused) cotton swab.

IX. LIMITATIONS

Lipid Profile·Glucose

A. The measuring range for total cholesterol is 100 - 500 mg/dL. Results outside this range will appear as <100 mg/dL or >500 mg/dL.
B. The measuring range for HDL cholesterol is 15 - 100 mg/dL. Results outside this range will appear as <15 mg/dL or >100 mg/dL.
C. The measuring range for triglycerides is 45 - 650 mg/dL. Results outside this range will appear as <45 mg/dL or >650 mg/dL.
D. If the triglycerides are >400 mg/dL, the estimated LDL will not be calculated.
E. If the total cholesterol, HDL cholesterol or triglyceride result is outside the measuring range, the LDL will appear as N/A.
F. If the triglycerides are >650 mg/dL, the HDL result may not be accurate and will appear as N/A. (Results of > 400 will affect the LDL calculated result.) Do not report LDL when triglyceride is > 400.
G. The measuring range for glucose is 50-500 mg/dL. Results outside this range will appear as <50 mg/dL or >500 mg/dL.
H. The glucose test is specific for D-glucose.
I. Other sugars that may be present in the blood do not react in the glucose test (i.e., fructose, lactose).
J. Glucose tests done at altitudes above 5,000 feet may give low results.
K. Samples with results outside of the measuring range must be sent to the Clinical Laboratory for testing.
L. Performance of the *Cholestech LDX* System has not been tested on samples of lipid profile and glucose from newborns.

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X. INTERFERING SUBSTANCES

Lipid Profile·Glucose

Some substances may cause false results with enzymatic tests. The substances listed below were tested for interference with the Lipid Profile/Glucose test. Less than 10% interference was seen at the levels shown.

Substance Concentration (mg/dL)

Hemoglobin	125.0		Gemfibrozil	15.0
L-Dopa	0.8		Bilirubin	5.0
Ascorbic Acid	1.0		Probucol	32.5
Urea	500.0		Nicotinic Acid	10.0
Fructose	30.0		Clofibrate	80.0
Uric Acid	15.0		Lovastatin	4.0
Creatinine	30.0		Dipyrone	10.0
Glutathione	1.0		Methotrexate	450.0
Cimetidine	7.5		Nitrofurantoin	2.0
Oxytetracycline	4.0		Gentisic Acid	0.5
Lactose	100.0		Methyldopamine	0.5
Cysteine	2.5			

A. Hematocrits between 30-52% do not affect results.
B. Blood collection tubes with glycerol should not be used for the triglyceride test.
C. Hand creams and soaps with glycerol may cause falsely high triglyceride results.
D. The triglyceride test measures triglycerides and free glycerol. Free glycerol usually is less that 20 mg/dL.
E. There may be a 6 – 7% difference in the glucose levels of fingerstick and venous blood.
F. Hematocrits between 30% and 50% do not affect results.

X. PRECAUTION

A. Gloves must always be worn when working with patient and control samples.
B. All blood samples and containers; capillary tubes and materials that have come in contact with blood should be handled as if capable of transmitting infectious disease and discarded into a biohazard waste container after use.

XI. REFERENCES

A. Cholestech LDX User Manual
B. UCSF Clinical Laboratory Manual
C. Cholestech LDX Lipid Profile plus Glucose Product Insert. 402 13495 REV. C 2008
D. Cholestech LDX Level 1 and Level 2 Control Product Insert ART10983B Rev. 0 350076-8 2007-03
E. Cholestech LDX Multi-Analyte Control Product Insert. ART14120 Rev. A 350456-6 2007-06
F. Cholestech online Technical Library: www.cholestech.com/support/library.htm
G. Cholestech Corporation, 3347 Investment Blvd. Hayward, CA 94545 1-800-733-7227